IN THE MATTER OF

* BEFORE THE

INSTITUTIONAL PHARMACY SERVICES

* STATE BOARD

Respondent-Pharmacy

OF

....

PHARMACY

PERMIT NUMBER: PW0058

CASE NO.: PI 11-060

FINAL CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board"), and subject to Md. Health Occ. Ann. § 12-101, et seq., (2009 Repl. Vol. and 2010 Supp.) (the "Act"), the Board charged Institutional Pharmacy, (the "Respondent-Pharmacy"), with violations of the Act. Specifically, the Board charged the Respondent-Pharmacy with violation of the following provisions:

- § 12-409. Suspension and Revocations-Grounds.
 - (a) In general Subject to the hearing provisions of § 12-411 of this subtitle, the Board, may suspend or revoke any pharmacy permit, if the pharmacy:
 - (1) Is conducted so as to endanger the public health or safety;
 - (2) Violates any of the standards specified in § 12-403 of this title; or
 - (3) Is otherwise not conducted in accordance with the law.

The Board also charged the Respondent-Pharmacy with violation of: § 12-403. Required Standards.

- (b) In general Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
 - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

- (3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;
- (4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation.

The Board also charged the Respondent-Pharmacy with violating the following: Code Md. Regs. tit. 10 § 34.05:

.02 Prescription Area.

- (A) The pharmacy permit holder shall:
 - (3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services;
 - (4) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.

The Board further charged the Respondent-Pharmacy with violation of: Code Md. Regs. Tit. 10 § 34.05:

- .03 Pharmacy Operation.
- (A) A pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation.

The Respondent-Pharmacy was given notice of the issues underlying the Board's charges by letter dated June 15, 2011. Accordingly, a Case Resolution Conference was held on September 28, 2011, and was attended by Richard Matens, P.D., and Meyer Handleman, P.D., Board members, YuZon Wu, P.D., Compliance Officer of the Board, and Linda Bethman, Counsel to the Board. Also in attendance were Ettore and James Tristani, owners of the Respondent-Pharmacy, and its attorney, Howard Schulman, and the Administrative Prosecutor, Roberta Gill.

Following the Case Resolution Conference, the parties and the Board agreed to resolve the matter by way of settlement. The parties and the Board agreed to the following:

FINDINGS OF FACT

- 1. At all times relevant herein, the Respondent-Pharmacy was originally issued a permit to operate as a pharmacy on or about March 3, 2004. The Respondent-Pharmacy's permit is due to expire on December 31, 2011.
 - 2. The Respondent-Pharmacy is located in Bel Air, Maryland.
 - 3. Pharmacists A and B are owners of Respondent-Pharmacy.
- 4. On November 14, 2010, the Maryland Division of Drug Control ("DDC") conducted a routine inspection of the Respondent-Pharmacy.
- 5. When the DDC arrived at the Respondent-Pharmacy, the Respondent-Pharmacy was open for business, but there was not a licensed pharmacist in the pharmacy area.
- 6. Subsequently, DDC notified the Board that the Respondent-Pharmacy was operating without a licensed pharmacist.
- 7. On November 18, 2010, the Board initiated an inspection of the Respondent-Pharmacy.
- 8. When the Board investigator arrived at the Respondent-Pharmacy, there was not a licensed pharmacist present.
- 9. The Board investigator arrived at the Respondent-Pharmacy at approximately 10 a.m.

- 10. The Board inspector spoke with Respondent-Pharmacy employees, who were present.
- 11. One employee, TS, a pharmacy technician, was filling cassettes for a drug and alcohol rehab facility
- 12. Another employee, BC, a pharmacy technician, was filling bubble packs for assisted living facilities and community patients.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated § 12-409 (a) (1), (2) and (3); § 12-403 (b) (1), (2), (3), and (4); Code of Md. Regs. tit. 10 §34.05.02 (A) (3) and (4); and § 34.05.03 (A).

<u>ORDER</u>

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this <u>Stranger</u>, 2011, by a majority of a quorum of the Board.

ORDERED that the Respondent-Pharmacy shall pay unto the Board a monetary penalty of \$2500 within 30 days of the effective date of said Order; and be it further

ORDERED, that the Respondent-Pharmacy shall be subject to random, unannounced inspections to verify that it is in compliance with all laws and regulations governing the operation of a pharmacy;

ORDERED that the Consent Order is effective as of the date of its signing by the Board; and be it

ORDERED that should the Board receive a report that the Respondent-Pharmacy has substantially violated the Act or if the Respondent-Pharmacy violates any conditions of this Order, after providing the Respondent-Pharmacy with notice and an opportunity for a hearing, the Board may take further disciplinary action against the Respondent-Pharmacy, including suspension or revocation. The burden of proof for any action brought against the Respondent-Pharmacy as a result of a breach of the conditions of the Order shall be on the Respondent-Pharmacy to demonstrate compliance with the Order or conditions; and be it

ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and be it further

ORDERED that for purposes of public disclosure, as permitted by Md. State Gov't. Code Ann. §10-617(h) (Repl. Vol. 2009 and 2011 Supp.), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law and Order and that the Board may also disclose same to any national reporting data bank that it is mandated to report to.

Michael N. Souranis, P.D., President

State Board of Pharmacy

CONSENT OF INSTITUTIONAL PHARMACY

I, ETTORE M. (DISTAN), co-owner/officer of the Respondent-Pharmacy, by affixing my signature hereto, acknowledge that:

- 1. I am represented by an attorney, Howard Schulman, and have been advised by him of the legal implication of signing this Consent Order;
- 2. I am aware that without my consent, the Respondent-Pharmacy's permit to operate as a pharmacy in this State cannot be limited except pursuant to the provisions of § 12-409 of the Act and the Administrative Procedure Act (APA) Md. State Govt. Code Ann. §10-201, et seq., (2009 Repl. Vol. and 2011 Supp).
- 3. I am aware that I am entitled to a formal evidentiary hearing before the Board

By this Consent Order, I hereby consent and admit to the foregoing Findings of Fact, Conclusions of Law and Order, provided the Board adopts the foregoing Consent Order in its entirety. By doing so, I waive my right to a formal hearing as set forth in § 12-411 of the Act and §10-201, et seq., of the APA, and any right to appeal as set forth in § 12-412 of the Act and §10-201, et seq., of the APA. I acknowledge that my failure to abide by the conditions set forth in this Order and following proper procedures, the Respondent-Pharmacy may suffer disciplinary action, possibly including revocation, against its permit to operate as a pharmacy in the State of Maryland.

Date

On behalf of Institutional Pharmacy

STATE OF MARYLAND
CITY/COUNTY OF Harford:
I HEREBY CERTIFY that on this <u>25th</u> day of <u>November</u> , 2011, before me, <u>Jerome D. Heathcott</u> , a Notary Public of the foregoing State and (City/County), (Print Name)
personally appeared <u>Ettore M Tristani</u> , License No. <u>06437</u> , and
made oath in due form of law that signing the foregoing Consent Order was his
voluntary act and deed, and the statements made herein are true and correct.
AS WITNESSETH my hand and notarial seal. Jerome D. Heathcott, Sr Notary Public
My Commission Expires: 08-08-2014